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Application News

Compact Table-Top Tester EZ Test™

# Strength Evaluation of Pharmaceuticals and PTP Packaging

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## User Benefits

- Enables strength evaluations required for the development and quality control of pharmaceuticals and PTP packaging.
- Meets test data integrity and audit trail requirements by using LabSolutions™ AG.

## ■ Introduction

In the development and quality control of pharmaceuticals and pharmaceutical packaging, it is necessary to ensure their efficacy and safety. Therefore, various evaluations are performed. For example, tablets must be hard enough to not crack or split during their manufacture and transport. But if they are too hard, their solubility when swallowed could be reduced, so they must be manufactured to the appropriate hardness. The packaging of pharmaceuticals must also protect them from moisture and light so that their quality does not deteriorate. Typically, pharmaceuticals are enclosed in plastic or aluminum using PTP sheets, and the packaging is designed to dispense them by pressing the sheet. Therefore, the packaging must be manufactured so that the force to push them out is appropriate. Testing machines are used to perform these evaluations.

Here the three types of tests used in the strength evaluations are introduced: compressive tests on pharmaceuticals, 3-point bend tests on pharmaceuticals, and push-out tests on PTP sheets to evaluate the strength of PTP packaging.

## ■ Measuring Device

Fig. 1 shows the EZ Test compact table-top tester. Various jigs can be fitted to EZ Test to enable different tests to be performed. The device configuration is shown in Table 1. The software used is LabSolutions AG, which can handle the data management for pharmaceuticals.

Fig. 1 EZ Test Compact Table-Top Tester

Table 1 Equipment Configuration

| | |
|---|---|
| Testing Machine: | EZ Test Compact Table-Top Tester |
| Load Cell: | 500 N |
| Jigs: | Compression test<br>Upper compression plate (φ25) / Lower compression plate (φ118)<br>Three-point bending test<br>Three-point bending test jig (R0.1 mm × W80 mm) / jig platform<br>Push-out test<br>Pill push-out jig set / jig platform |
| Software: | LabSolutions AG |

## ■ Compression Test

Fig. 2 shows a compression test being performed on a tablet. In the reference information in the 18th edition of the Japanese Pharmacopoeia, which was amended in 2021, a tablet hardness test method was introduced. It states that the orientation of the tablet test specimen "shall enable compression across the diameter of the tablet." Therefore, the tablet test specimen was placed in the diametral direction and compressed from above with a cylindrical pressing jig. The test speed was set to 1 mm/min.

The test results are shown in Fig. 3. After the tablet test specimens were subjected to a maximum force of approximately 100 to 120 N, a crack formed parallel to the force direction, and the test was terminated. Fig. 4 shows the tablet test specimens after testing.

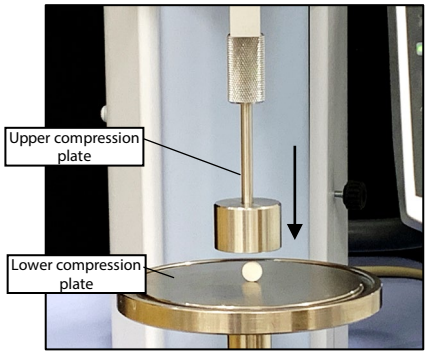


Fig. 2 Tablet Compression Test

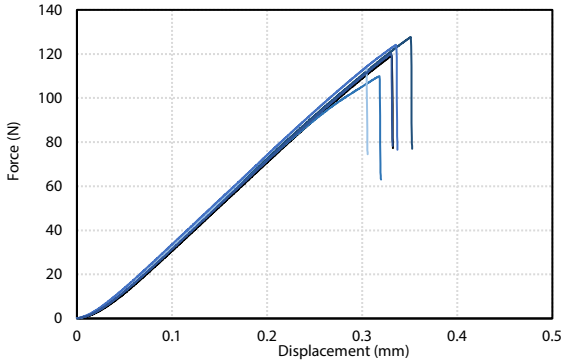


Fig. 3 Tablet Compression Test Results
(Force - displacement graph for six tests)

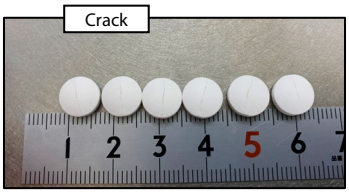


Fig. 4 Tablet Test Specimens after Testing

## ■ Three-Point Bending Test

Fig. 5 shows a three-point bending test being performed on a tablet. The tablet test specimen was placed onto the support points (the distance between the support points was 2 mm), and the force was applied from above with a punch. The test speed was set to 5 mm/min. The three-point bend test for tablets is described in Chapter <1217> of the United States Pharmacopeia.

Test results are shown in Fig. 6. The tablet test specimens used in this example each had a maximum force from 90 to approximately 100 N. A crack then formed in the center of the tablet, and the test was terminated.

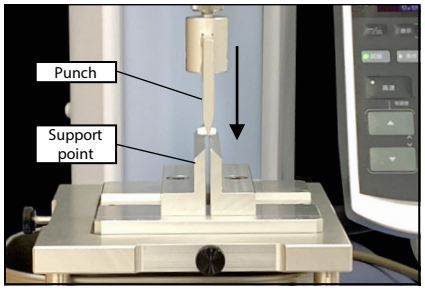


Fig. 5 Three-Point Bending Test

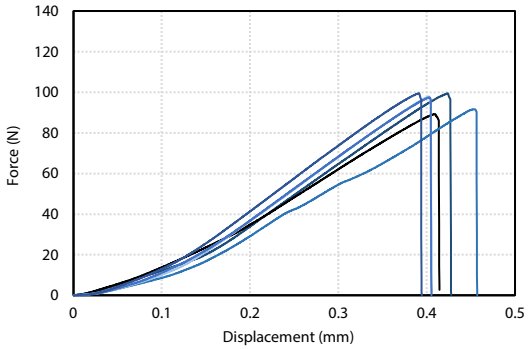


Fig. 6 Tablet Three-Point Bending Test Results
(Force - displacement graph for six tests)

## ■ Push-Out Test

The test setup for a PTP packaging push-out test is shown in Fig. 7. A tablet and a capsule packaged in a PTP sheet were used. Adapters for four different shapes of hole are provided in the jig set, and an adapter suitable for the test specimen can be selected. The packaged test specimen was placed over the hole, a force was applied from above by a punch, and the pharmaceutical was pushed out of the PTP sheet. The test speed was set to 10 mm/min.

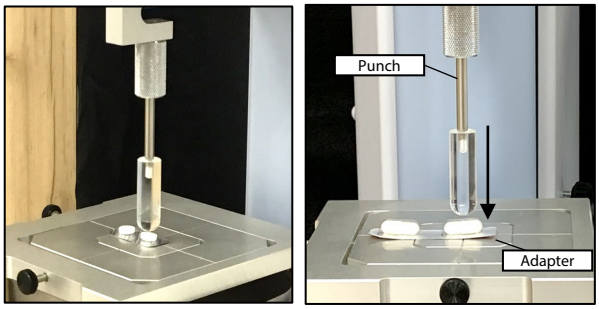


Fig. 7 Push-Out Test from PTP Packaging
(Left: Tablet, Right: Capsule)

The test results are shown in Fig. 8. In the tests a tear formed in the aluminum part of the PTP sheet, and the test was terminated when the force dropped below a certain level. The maximum force for the tablet and the capsule used here was different. A judgment can be made whether the tablet can be easily pushed out of the packaging using the maximum force, and this data can be used in product development and quality control.

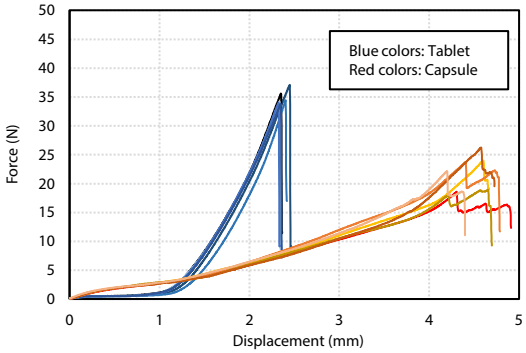


Fig. 8 Results of Push-Out Test from PTP Packaging
(Force - displacement graph for six tests each)

## ■ LabSolutions AG

LabSolutions AG Autograph software uses the management functions of the analysis data management tool LabSolutions DB/CS, and it can comply with the U.S. FDA 21CFR Part 11 and the Japanese ER/ES regulations for electronic records and electronic signatures.
Specifically, it includes the following functions:

- Detailed user authorization allocating test types and operation details that each user can perform
- Audit trails that record different users or details and reasons as a history when test conditions are changed (Fig. 9)
- A set of reports that can manage compilations of test specimen information, operation histories, test results, and approvals

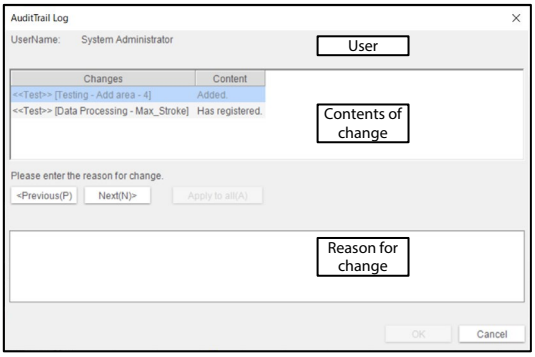


Fig. 9 Audit Trail Log Window

## ■ Conclusion

Strength evaluations of pharmaceuticals and PTP packaging were performed using the EZ Test compact table-top tester. By selecting from the various jigs available, tests can be performed in accordance with the purpose of evaluation, such as compression tests, three-point bending tests, and push-out tests. In addition, by using LabSolutions AG, it is possible to comply with data integrity requirements, prevent test data tampering, and improve the efficiency of the work.



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